K063562 1/2

Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

Submitted by:

Patrice Napoda
Mgr. Regulatory Affairs
Ethicon, Inc., A *Johnson & Johnson* Company
Route 22 West, PO Box 151
Somerville, NJ 08876

FEB 26 2007

Name/Classification of Device:

Class II in 21 CFR § 878.3300, Surgical Mesh (OTP)
Class II in 21 CFR§ 884.3900, Vaginal Stent
Class I in 21 CFR § 880.6960 Irrigating syringe
Class I in 21 CFR § 878.4800 Manual surgical instrument for general use

Trade Name:

GYNECARE PROSIMA* Pelvic Floor Repair Systems

Predicate Devices:

GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh
Silimed Vaginal Stent

Statement of Intended Use:

The GYNECARE PROSIMA Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Implants, are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor, either as mechanical support or bridging material for the fascial defect. The Systems provide maintenance of the vaginal canal during the period of healing following surgical repair of vaginal wall prolapse, while supporting the position of the Mesh Implants.

DESCRIPTION

The GYNECARE PROSIMA Anterior, Posterior, and Combined Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH PS Mesh Implant(s), and instruments to facilitate Mesh Implant placement and postoperative support. The following table summarizes the components included with each System:

PELVIC FLOOR REPAIR SYSTEM	COMPONENTS				
	Mesh Implant in Carrier (A)	Vaginal Support Device – Balloon Assembly (B&C)	Anterior Inserter (D)	Posterior Inserter (E)	Syringe (F)
Anterior	1	1	1		1
Posterior	1	1		1	1
Combined	2	1	1	1	1

Summary of Technological Characteristics of New Device to Predicate Devices:

The modified device has similar technological characteristics to those of the predicate devices. Like currently marketed devices, the system contains a sterile, mesh implant made from GYNECARE GYNEMESH* PS Nonabsorbable Prolene Soft Mesh and is intended for the repair of fascial structures of the pelvic floor. Like several of the currently marketed devices, the mesh implant within the proposed device is made of nonabsorbable polymers. The polymers used are identical to those found in GYNECARE GYNEMESH* PS Nonabsorbable Prolene Soft Mesh, currently marketed by Ethicon, Inc.

The Vaginal Support Device-Balloon Assembly of the system, as in the predicate vaginal stent, provides support to the vaginal canal after surgery, thus reducing the possibility of contracture, stenosis and vaginal canal adhesions. The balloon portion of the assembly is inflated with air, similar to the predicate device, filling the vaginal canal space for the first twenty-four hours. The Vaginal Support Device of the assembly is made of silicon, as is the predicate device, and remains in the vaginal canal for up to four weeks, providing continuing support to the vagina and the Mesh Implants as tissue in-growth occurs. The predicate vaginal stent is intended to remain in the vaginal canal for up to twelve weeks while tissue healing occurs.

Performance Data:

Biological reactivity of the materials has been assessed using methods specified in ISO Standard 10993-1, with results to date demonstrating that the materials are acceptable for the intended use. Results of functional performance testing (bench and cadaver testing) indicate that the proposed device meets or exceeds all functional requirements.

Conclusions:

Based on the similarities to the predicate devices identified in this submission, we conclude that the modified device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.

* *Trademark of Ethicon, Inc.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Patrice Napoda
Sr. Project Manger
Ethicon, Inc.
Route 22 West, P.O. Box 151
SOMERVILLE NJ 08876

SEP 28 2012

Re: K063562
Trade/Device Name: GYNECARE PROSIMA* Pelvic Floor Repair Systems
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: January 25, 2007
Received: January 26, 2007

Dear Ms. Napoda:

This letter corrects our substantially equivalent letter of February 26, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

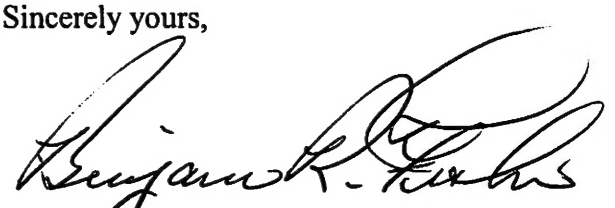
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K063562

Indications for Use

510(k) Number (if known): K063562

Device Name: GYNECARE PROSIMA* Pelvic Floor Repair Systems

Indications for Use:

The GYNECARE PROSIMA* Pelvic Floor Repair Systems, through the placement of GYNECARE GYNEMESH* PS Nonabsorbable PROLENE Soft Mesh, are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor, either as mechanical support or bridging material for the fascial defect. The Systems provide maintenance of the vaginal canal during the period of healing following surgical repair of vaginal wall prolapse, while supporting the position of the Mesh Implants.

*Trademark.

Prescription Use X . AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063562